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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,456	08/21/2002	Israel Raleigh Lurie	Q68463	3880

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,456	LURIE ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 23-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office Action is responsive to the amendment filed August 31, 2005.

Claims 23-44 are pending. Claims 25-26, 32-35, 37, 40 and 42-43 are amended. No claims have been cancelled. Claim 44 has been added.

Specification

2. Objection is withdrawn due to amendment.

Claim Objections

3. Regarding claims 33-35 and 40, the objections are withdrawn due to amendment.

Claim 42 is objected to because of the following informalities:

At line 2, "extocervical" should read --ectocervical--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in the action can be found in a prior Office action.

Regarding claims 25-26, 32, 34 and 37-42, the rejections are withdrawn due to amendment.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite. It is unclear whether Applicant inappropriately attempts to combine two statutory types of invention. The preamble of the claim recites a method however line 2 of the claim defines an apparatus for collection of a fluid.

Claim 43 recites the limitation "the end" in line 11 of the claim. There is insufficient antecedent basis for this limitation prior to this recitation. It is unclear as to what end of the catheter the recitation refers (i.e. the proximal or distal end of the catheter).

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in the action can be found in a prior Office action.

6. Claims 23-25, 32, 35 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellard (US Patent No. 5,007,903).

Regarding claim 23, Ellard discloses a device 10 for collection of a fluid sample, comprising a barrel 12 having an opening 37 at one end thereof, a plunger 16 operable axially within the barrel 12; the barrel 12 and the plunger 16 defining a fluid chamber having a volume which varies on axial movement of the plunger 16 within the barrel 12, and a flexible, hollow, elongate catheter 28 extending from the fluid chamber through the opening 37 in the barrel 12, the catheter being in operative engagement with the plunger 16 for axial movement to extend and retract the catheter 28 within respect to the barrel 12 on axial movement of the plunger 16, and said catheter 28 being in fluid communication with the fluid chamber to provide a fluid flow path to and from the fluid chamber through the hollow catheter 28 (see fig. 1).

Regarding claim 24, Ellard discloses a device 10, as described above, wherein the catheter 28 extends into a chamber in the plunger 16 which is in fluid communication with said fluid chamber (see fig. 1).

Regarding claim 25, Ellard discloses a device 10, as described above, wherein the catheter 56 is provided with perforations 60 in the wall thereof at or near the end thereof attached to the plunger for fluid communication with said fluid chamber (see fig. 3).

Regarding claim 32 and 44, Ellard discloses a device 10, as described above, further comprising a coil spring device 40 located between the barrel 12 and the plunger 16 of the device 10 (see fig. 2).

Regarding claim 35, Ellard discloses a device 10, as described above, further comprising means for collection (the capsule defined by reference numerals 48 and 51) of a sample of cells or cellular debris, the means being located on said barrel 12 at or adjacent to the opening 47 at one end thereof (see column 3/lines 51-56 and column 4/lines 28-35; see fig. 3).

7. Claims 23, 26, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahurkar (US Patent No. 5,836,921).

Referring to claim 23, Mahurkar discloses a device for collection of a fluid sample, comprising a barrel 10 having an opening 15 at one end thereof, a plunger 11 operable axially within the barrel 10, the barrel 10 and the plunger 11 defining a fluid chamber having a volume which varies on axial movement of the plunger 11 within the barrel 10, and a flexible, hollow, elongate catheter 13 extending from the fluid chamber

through the opening 15 in the barrel 10, the catheter 13 being in operative engagement with the plunger 11 for axial movement to extend and retract the catheter 13 within respect to the barrel 10 on axial movement of the plunger 11, and the catheter 13 being in fluid communication with the fluid chamber to provide a fluid flow path to and from the fluid chamber through the hollow catheter 13 (see figs. 4 & 5).

Referring to claim 26, Mahurkar discloses a device, as described above, wherein the end of the catheter 13 remote from the plunger 11 is sealed, and the catheter 13 is provided with perforations 26 in the wall thereof at or near the sealed end of the hollow catheter 13 (column 5/lines 1-3).

Referring to claim 33, Mahurkar discloses a device, as described above, further comprising means to rotate the plunger 11 on axial movement of the plunger 11 within the barrel 10 of the device (column 7/lines 48-50).

Referring to claim 34, Mahurkar discloses a device, as described above, wherein the means to rotate is adapted to rotate the plunger from 90° to 360° on full axial movement of the plunger 11 within the barrel 10 (i.e. the plunger 11 rotates according to the curvature of slot 19; see fig. 1).

8. Claims 37-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravlee (US Patent No. 3,636,940).

Regarding claim 37, Gravlee discloses a method for collection of a fluid sample from an internal cavity of a mammal, the method comprising the steps of:

(i) locating the end of a flexible, hollow, elongate catheter (i.e. defined by two lumens 21 and 23) at the opening of the internal cavity;

(ii) penetrating the internal cavity by moving the catheter into the cavity while simultaneously passing wash fluid through the hollow catheter (i.e. through the inlet lumen 21) to wash at least a portion of the surface of the internal cavity; and

(iii) subsequently retracting the catheter from the cavity while simultaneously collecting a fluid sample by aspirating the wash fluid through the hollow catheter (i.e. through the outlet lumen 23) (see column 2/lines 71-75; see column 4/lines 112-15; see abstract).

Regarding claim 38, Gravlee discloses a method, as described above, wherein the mammal is a human.

Regarding claim 39, Gravlee discloses a method, as described above, wherein the internal cavity is the uterus 36 of a human female, and the fluid is a uterine wash sample 32 (see figs. 1 & 2; column 2/lines 71-75).

Regarding claim 40, Gravlee discloses a method, as described above, comprising the further step of substantially separating out the fluid sample from the cells and cellular debris (see column 4/lines 12-15 and 67-70).

Regarding claim 41, Gravlee discloses a method, as described above, wherein a sample of cells or cellular debris is simultaneously collected at the opening of the internal cavity (see fig. 2).

Regarding claim 42, Gravlee, discloses a method, as described above, wherein the sample is a sample of ecto- and/or endo-cervical cells (see fig. 2).

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in the action can be found in a prior Office action.

10. Claims 27-28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Sundberg (US Patent No. 5,494,044).

Ellard discloses a device, as described above, that teaches all the limitations of the claim except that it does not further comprise a filter. Sundberg discloses a syringe with a cell filter 17 located in the barrel 10 in the fluid flow path to and from the fluid chamber through the hollow catheter 15; the cell filter 17 is adapted to substantially remove cells and cellular debris from a fluid in said fluid flow path (see column 5/lines 34-35, 57-60). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Ellard with a filter similar to that of Sundberg in order to perform in-vivo separation of bodily fluids from cells (i.e. simultaneous collection and filtering operations).

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Sundberg ('044) as applied to claim 27 above, further in view of Schindler et al. (US Patent No. 4,265,249). The device of Ellard as modified by Sundberg discloses all the limitations of the claim except that the filter is not located in the hollow catheter. Schindler et al. disclose a catheter device wherein a filter is positioned in hollow catheter. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Ellard as modified by Sundberg with a filter located in the hollow catheter in order to

remove the cells from the body fluid directly inside the body of the patient (column 1/lines 61-64).

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Sundberg ('044) as applied to claim 27 above, further in view of Baidwan et al. (US Patent No. 5,238,003). The device of Ellard as modified by Sundberg discloses all the limitations of the claim except that the filter is not located in the plunger. Baidwan et al. disclose a syringe with a filter located in the plunger (see figs. 1 & 2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Ellard as modified by Sundberg with a filter located in the plunger, which controls the volume of fluid to be collected, so as to maximize the capacity of the fluid chamber of the syringe (i.e. when the filter is located in the barrel, less fluid can be collected with a similar size syringe compared to when the filter is located in the plunger) (see column 1/lines 18-22).

13. Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellard ('903) in view of Parasher (US Patent No. 5,738,109). Ellard discloses a device, as described above, that teaches all the limitations of the claim except that the means for collecting a sample of cells or cellular debris comprises a brush or brush-like device. Parasher discloses a medical catheter with a brush located near a distal end for insertion into a body cavity for collecting a sample of cells or cell debris. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Ellard with a cell collection catheter similar to that of Parasher in order to obtain a large sample of cells that qualifies as a biopsy

without the risk of damaging the endo-cervical canal (see Parasher, column 2/lines 17-20 and 31-36).

Response to Arguments

14. Applicant's arguments filed August 31, 2005 have been fully considered but they are not persuasive. Applicant contends that Ellard ('903) and Mahurkar ('921) both fail to teach or suggest a flexible, hollow, elongate catheter that is capable of following the internal conformation of an internal cavity of a mammal when the device is used for collection of a fluid sample from such an internal cavity. Applicant further contends that Gravlee does not disclose a single catheter rather a device with separate inlet and outlet tubes which are not disclosed as being flexible. Moreover, Applicant argues that the Gravlee device uses a source of suction or negative pressure to cause the washing solution to pass through the inlet tube into the body cavity and then pass through the outlet tube into the collection point whereas Applicant's instant device operates using both positive pressure to simultaneously pass wash fluid through the hollow catheter as the catheter is moved into the cavity as well as negative pressure to simultaneously collect a fluid sample through the hollow catheter is retracted from the cavity in order to more efficiently wash the internal cavity since the fluid is sprayed through the catheter under positive pressure as the catheter is moved into the cavity. These arguments have been fully considered but are not persuasive.

15. Regarding Applicant's argument that Ellard and Mahurkar both fail to teach or suggest a flexible, hollow, elongate catheter that is capable of following the internal conformation of an internal cavity of a mammal when the device is used for collection of

a fluid sample from such an internal cavity, the Examiner respectfully disagrees. The Examiner notes that the claim language only requires a flexible, hollow, elongate catheter. In response to applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e. that the flexible, hollow, catheter be capable of following the internal conformation of an internal cavity of a mammal) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns,* 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The term "flexible" is defined by *Webster's II New Riverside University Dictionary (1994)* to mean "capable of being flexed or bent," "susceptible to influence," and "responsive to change," The Examiner notes that none of these definitions require the term "flexible" to mean capable of tracking a curved path or conformation. As such, the devices of Ellard and Mahurkar appear to meet the limitation of "flexible catheter" in that the various devices each appear to be capable of being bent.

16. Regarding Applicant's argument that Gravlee does not disclose a single catheter but a device with separate inlet and outlet tubes which are not disclosed as being flexible, the Examiner respectfully submits that the claim language does not require that there be only a catheter body comprising a single lumen. Moreover, the Examiner notes that column 3, lines 14-17 of the Gravely reference discloses an embodiment of the lumens 21 and 23 defining a single body or catheter. Furthermore, column 3, lines 7-10 of the Gravely reference teaches that the tubes 21 and 23 are made of a plastic material. The term "plastic" is defined by *Webster's II New Riverside University*

Dictionary (1994) to mean "easily influenced," "made of a plastic," and "capable of undergoing continuous deformation without rupture or relaxation," in light of the latter definition, the Examiner respectfully submits that the inlet and outlet tubes of Gravlee are flexible.

17. With regards to Applicant's argument that the Gravlee device uses a source of suction or negative pressure to cause the washing solution to pass through the inlet tube into the body cavity and then pass through the outlet tube into the collection point whereas Applicant's instant device operates using both positive pressure to simultaneously pass wash fluid through the hollow catheter as the catheter is moved into the cavity as well as negative pressure to simultaneously collect a fluid sample through the hollow catheter is retracted from the cavity in order to more efficiently wash the internal cavity since the fluid is sprayed through the catheter under positive pressure as the catheter is moved into the cavity, the Examiner respectfully traverses. The Examiner notes that the claim language only requires simultaneously passing wash fluid through the hollow catheter and simultaneously collecting a fluid sample by aspirating the wash fluid through the hollow catheter. In response to applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e. operating the device simultaneously using both positive and negative pressures) are not recited in the rejected claim(s). As such, the method of Gravlee appears to meet the limitation of "simultaneously passing washing fluid...while simultaneously collecting a fluid sample by aspirating..." in that the method of Gravlee teaches passing wash fluid through the hollow catheter (i.e. through

the inlet lumen 21) and subsequently collecting a fluid sample by aspirating the wash fluid through the hollow catheter (i.e. through the outlet lumen 23).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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